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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,880	02/24/2004	Agathe Subtil-Sands	249179US0	1685

22850 7590 04/23/2007

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
MINNIFIELD, NITA M	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/23/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/23/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
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Office Action Summary	Application No.	Applicant(s)	
	10/784,880	SUBTIL-SANDS ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-113* is/are pending in the application.

4a) Of the above claim(s) *3,5,6,15,16,26-47 and 49-113* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,7-14,17-25 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 5pgs

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-14, 17-25, 48-57, 60-62, 80-88 and 91-93) and species election of CPn0853 (SEQ ID NO: 60) in the reply filed on December 29, 2006 is acknowledged. The traversal is on the ground(s) that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctness between the identified groups has shown that a burden exists in searching all of the claims. While the Examiner has indicated a number of reasons why the inventions are separate and distinct or unrelated, she has provided no references to support these conclusions.

This is not found persuasive because there is no requirement in MPEP 800 to provide a reference to support the conclusions of separate and distinct inventions. "The burden is on the examiner to provide an example to support the determination that the inventions are distinct, *but the example need not be documented.* If applicant either proves or provides convincing evidence that the example suggested by the examiner is not workable, the burden is on the examiner to suggest another viable example or withdraw the restriction requirement. See MPEP 806.05 (h) or MPEP 806.05 (j) It is noted that Applicants have not provided any convincing evidence that the examples suggested by the examiner are not workable.

The traversal is on the grounds that a search of all the claims would not impose a serious burden on the office.

This is not found persuasive. As to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not

co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist. There is a search burden on the Office to search the 41 different amino acid sequences of polypeptides as recited in claim 1 for example or the 41 different polynucleotide acid sequences that encode the 41 different polypeptides as recited in claim 15 for example.

The Office acknowledges Applicants' request for rejoinder of an allowable product and with the method of using this product in diagnosing, detecting or screening and allow these methods with the product in accordance with the rejoinder procedures of M.P.E.P. § 821.04(a).

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 3, 5, 6, 15, 16, 26-47 and 49-113 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 29, 2006.

3. Claims 1, 2, 4, 7-14, 17-25 and 48, directed to the claimed invention and species election, will be examined in the instant application.

4. The disclosure (see p. 22 for example) is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

5. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 recites the limitation "said respiratory disease" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 18 does not recite a respiratory disease.

6. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure for the claimed invention. The specification, at p. 21, lines 4-16, sets forth "An ipaB mutant strain of S. flexneri expresssing IncA/cya was deposited at C.N.C.M., 25, Rue de Docteur Roux, F-75724, Paris Cedex 15, France, on December 13, 2000, with accession number 1-2592. A bacterial strain containing the vector pUC19cya was deposited at C.N.C.M., 25, Rue de Docteur Roux, F-75724, Paris Cedex 15, France, on December 13, 2000, with accession number 1-2593. An ipaB" mutant strain of S. flexneri designated SF620 was deposited at C.N.C.M., 25, Rue de Docteur Roux, F-75724, Paris Cedex 15, France, on December 13, 2000, with accession number 1-2594. A E. coli bacterial strain containing Psi0710 in an expression vector (pQE trisystem, Qiagen) with a carboxy-terminal Histidine tag was deposited at C.N.C.M., 25, Rue de Docteur Roux, F-75724, Paris Cedex 15, France, on February 18, 2003, with accession number 1-2974."

It appears that these cells are necessary to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, a deposit of the above plasmid may satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See 37 C.F.R. 1.802.

It is noted that the plasmid has been deposited. However, the certificate of deposit has not been provided nor have the statements of assurance been made, see below. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If the deposits have not been made under the provisions of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository (with address) and that the following criteria have been met:

(a) during the tendency of the application, access to the deposits will be afforded to one determined by the Commissioner to be entitled thereto;
(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;
© the deposits will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
(d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

7. Applicant is reminded that the following and should amend the specification (see pp. 22-23) accordingly.

The current address of the ATCC is as follows:
American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

8. Claims 18-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a vaccinating composition against Chlamydia infection (infection contributes to atherosclerosis, infection is sexually transmitted disease, infection is respiratory disease or infection is bronchitis) wherein said composition comprises at least one polypeptide according to Claim 1 or an immunogenic fragment thereof along with a pharmaceutically acceptable carrier.

The specification does not enable the claimed invention. The specification does not set forth any examples or guidance sufficient to teach a person of skill in the art how to use the claimed vaccinating composition (comprising a *Chlamydia pneumoniae* polypeptide and pharmaceutically acceptable carrier) against *Chlamydia* infection and specifically infection contributes to atherosclerosis, infection that is sexually transmitted disease, infection that is respiratory disease or infection that is bronchitis. It is noted that the state of the art teaches that the claimed invention a vaccine to protect against *Chlamydia* infection, is unpredictable.

The state of the art teaches that *Chlamydia pneumoniae* has been associated with a broad spectrum of diseases including sinusitis, bronchitis, community-acquired pneumonia, chronic obstructive pulmonary disease, asthma, cardio-vascular disease, multiple sclerosis and Alzheimer's disease and that *Chlamydia trachomatis* has been associated with trachoma, lymphogranuloma venereum and sexually transmitted disease (see Murdin et al 2004, p. 1; see also Birkelund et al, In: New Bacterial Vaccines, editor Ellis et al, 2003, pp. 93-109). Murdin et al teaches that in 1966 in was concluded that although some vaccines now being tested are partially effective, much remains to be learned about immunity to trachoma and methods of inducing it artificially (citation omitted). And that in 2004 skeptics might argue that nothing has changed. Candidate *C. trachomatic* and *C. pneumoniae* vaccines are at best partially effective in animals and have not been tested in humans, the nature of protective immune responses is only partially defined, and methods of eliciting protection in animal models are arrived at empirically following strategies that may not be acceptable or effective for human use. This criticism is, of course, too harsh, but does highlight the often frustrating

lack of progress caused by the unusually difficult challenges inherent to *Chlamydia* vaccine development (citation omitted)." (p. 7, column 2) Puolakkainen et al 1999 teaches, for example, that the selection of the *C. pneumoniae* vaccine antigen is problematic since there has been no information on the specificity of the protective immunity (p. 976, column 1). Thorpe et al (Vaccine, 2007, 25:2252-2260) teaches that "[D]espite of the prominence of the Chlamydiae in a wide variety of serious human diseases there are currently no effective vaccines. Treatment is by antibiotic therapy, but patients often present with severe or irreversible complications and the use of antibiotics does not necessarily ameliorate established pathology (citation omitted). Unfortunately not only do untreated Chlamydial infections frequently lead to sequelae, but treatment persistence is thought to constitute a major factor in the pathogenesis of Chlamydial infections (citation omitted). Hence, even a partially effective vaccination programme would be less costly than a screening programme (citation omitted) and would cause a rapid and beneficial reduction in the prevalence of infection." (pp. 2252-2253) Finco et al (Vaccine , 2005, 23:1178-1188) teaches that in "spite of years of efforts by several research groups around the world, a vaccine against human chlamydial infection is so far unavailable, and, after the unsatisfactory results obtained with single antigens, it is now a currently accepted view that effective anti-*Chlamydia* immunization would be probably achieved only by balanced combinations of several antigens. Therefore, according to this viewpoint, the large amount of new information made available by recent genomic and proteomic studies has now opened new perspectives for the development of effective anti-*Chlamydia* vaccination." (pp. 1178-1179)

The amount of direction or guidance presented in the specification and the absence of working examples, of the claimed polypeptides of the vaccine, is a hindrance to practicing the claimed invention. Applicants have not provided guidance in the specification toward the teaching of protection against any and all *Chlamydia* infections. One skilled in the art would not accept on its face in view of the lack of examples given in the specification as being representative of the success in making and using the claimed invention in view of the lack of guidance in the specification and the known unpredictability associated with the ability to protect against all *Chlamydia* infections as well as those specifically claimed infections. The quantity of experimentation required to practice the invention as claimed would require the de novo determination of accessible target sites, modes of delivery and formulations of the claimed vaccine. Since the specification fails to provide particular guidance for the use of the vaccine and the art teaches that this is not yet possible (i.e. highly unpredictable), it would require undue experimentation to practice the invention as presently claimed.

Further, the specification would have been enabling as of the filing date involves consideration of the nature of the invention, the state of the prior art and the level of skill in the art. The state of the art is what one skilled in the art would have known, at the time the application was filed, about the subject matter to which the claimed invention pertains. The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed. The specification must be enabling as of the filing date, not evidence provided several years after the date of filing. The state of the art for a given technology is not static in time. It is entirely possible that a disclosure filed on January 2, 1990, would not have been enabled.

However, if the same disclosure had been filed on January 2, 1996, it might have enabled the claims. Therefore, the state of the prior art must be evaluated for each application based on its filing date. (see MPEP 2164.05(a))

There are many factors (In re Wands, 858 F.2d at 737, 8 USPQ2d) to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims is quite broad in view of the scope of *Chlamydia* infections and the lack of enablement in the specification and unpredictability in the state of the art. The nature of the invention and the state of the art has been described above. The level of one of ordinary skill is high (PhD level). The art is unpredictable as previously indicated. With regard to factors 6 and 7, the specification does not provide sufficient direction and the working examples do not enable the claimed invention; which in turn would require undue experimentation (factor 8) to practice the claimed invention. A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). In view of all of the above, the pending specification

does not enable the claimed invention and therefore the pending claims are not enabled.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1, 2, 4, 7-14, 17-25 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffais (WO 99/27105 6-1999; reference not provided).

Griffais discloses the claimed *Chlamydia pneumoniae* polypeptide (see below) and that the polypeptides can be used in immunogenic compositions and as

vaccines (abstract). The vaccines can be used to treat or prevent infections caused by *Chlamydia pneumoniae*, such as respiratory diseases, pneumonia, bronchitis, heart disease, and sarcoidosis (abstract).

It is noted that claims 7-14 are product by process claims. Although the reference appears to disclose the same purified proteins claimed by applicants, the reference does not disclose the proteins **produced** by the claimed process. However, the purification or production of a protein by a particular process does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art. This is particularly true when the properties of the protein are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular **process** used to prepare a protein is novel and unobvious over the prior art, the protein per se, even when limited to the particular process, is unpatentable over the same protein taught by the prior art. See In re King, 107 F.2d 618, 620, 43 U.S.P.Q. 400, 402 (C.C.P.A. 1939); In re Merz, 97 F.2d 599, 601, 38 U.S.P.Q. 143, 144-45 (C.C.P.A. 1938); In re Bergy, 563 F.2d 1031, 1035, 195 U.S.P.Q. 344, 348 (C.C.P.A. 1977) vacated 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 U.S.P.Q. 529, 543 (D.N.J. 1979).

However, even if applicants' protein is of higher purity than that of the prior art protein, applicants' protein would have been prima facia obvious over the protein of the prior art since one of ordinary skill in the art, being motivated by the expectation of success and the attainment of greater specific activity with increased purity, could have used conventional techniques in the protein art to further purify and characterize the protein.

The recitation of "vaccinating composition" (see claims 18-23) is viewed as intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Since the Patent Office does not have the facilities for examining and comparing applicants' polypeptide and compositions with the polypeptide and compositions of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed polypeptide and compositions and the polypeptide and compositions of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

OS Chlamydophila pneumoniae.
PN WO9927105-A2.
PD 03-JUN-1999.
PF 20-NOV-1998; 98WO-IB001890.
PR 21-NOV-1997; 97FR-00014673.
PR 04-NOV-1998; 98US-0107078P.
PA (GEST) GENSET.
PI Griffais R;
DR WPI; 1999-357842/30.
PT Genome sequence of Chlamydia pneumoniae
Query Match 100.0%; Score 1939; DB 2; Length 391;
Best Local Similarity 100.0%; Pred. No. 2.1e-172;
Matches 389; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy       1 MHPKIEKRNSLPLTAVAPVFEESYHPSVATTVDYVDATTLSRHLTVLKDVIKEARNLDLG 60
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Db       3 MHPKIEKRNSLPLTAVAPVFEESYHPSVATTVDYVDATTLSRHLTVLKDVIKEARNLDLG 62

Qy      61 KAFLTSMKQGFINTGTELAIIQASLADQSSRESRKKEEKIFHQHLGKAAPQAATATSGVQ 120
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Db      63 KAFLTSMKQGFINTGTELAIIQASLADQSSRESRKKEEKIFHQHLGKAAPQAATATSGVQ 122

Qy     121 PTADPVADKMPLQSAFAYVLLDKYIPAQEEALYALGRELNLSGYAQNLFSPLLDMIKSFN 180
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     123 PTADPVADKMPLQSAFAYVLLDKYIPAQEEALYALGRELNLSGYAQNLFSPLLDMIKSFN 182

Qy     181 SAPINYNLGSYISQTSGTANFAYGYEMILSRYNNEVSQCRLDIASTVKAKAALANMSASV 240
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Db    183 SAPINYNLGSYISQTSGTANFAYGYEMILSRYNNEVSQCRLDIASTVKAKAALANMSASV 242

Qy    241 KANVSLTDAQKKQIEDIIASYTKSLDVIHTQLTDVMTNLASITFVPGLNKYDPSYRIVGG 300
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Qy    301 DLSIIALQNDEKVLVDGKVDITTAVNEGGLLNFFTTVLTDVQNYGDLAQTQQLMLDLELK 360
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Qy    361 AMQQQWSLVSASLKLLNGMYTTVISGFKN 389
          ||||||||||||||||||||||||||||||
Db    363 AMQQQWSLVSASLKLLNGMYTTVISGFKN 391
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11. Claims 1, 2, 4, 7-14, 17-25 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffais (6559294) or Stephens et al (6822071).

Griffais, for example, discloses the claimed *Chlamydia pneumoniae* polypeptide (see below) and that the polypeptides can be used in immunogenic compositions and as vaccines (abstract; [279]; [280]; [271]). The vaccines can be used to treat or prevent infections caused by *Chlamydia pneumoniae*, such as respiratory diseases such as asthma, pneumonia or bronchitis, cardiovascular diseases, and atherosclerosis ([252]; [261], [10]; [12]; [15]),

It is noted that claims 7-14 are product by process claims. Although the reference appears to disclose the same purified proteins claimed by applicants, the reference does not disclose the proteins **produced** by the claimed process. However, the purification or production of a protein by a particular process does not impart novelty or unobviousness to a protein when the same protein is taught by the prior art. This is particularly true when the properties of the protein are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular **process** used to prepare a protein is novel and unobvious over the prior art, the protein per se,

even when limited to the particular process, is unpatentable over the same protein taught by the prior art. See In re King, 107 F.2d 618, 620, 43 U.S.P.Q. 400, 402 (C.C.P.A. 1939); In re Merz, 97 F.2d 599, 601, 38 U.S.P.Q. 143, 144-45 (C.C.P.A. 1938); In re Bergy, 563 F.2d 1031, 1035, 195 U.S.P.Q. 344, 348 (C.C.P.A. 1977) vacated 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 U.S.P.Q. 529, 543 (D.N.J. 1979).

However, even if applicants' protein is of higher purity than that of the prior art protein, applicants' protein would have been prima faciae obvious over the protein of the prior art since one of ordinary skill in the art, being motivated by the expectation of success and the attainment of greater specific activity with increased purity, could have used conventional techniques in the protein art to further purify and characterize the protein.

The recitation of "vaccinating composition" (see claims 18-23) is viewed as intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Since the Patent Office does not have the facilities for examining and comparing applicants' polypeptide and compositions with the polypeptide and compositions of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed polypeptide and compositions and the polypeptide and compositions of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

GENERAL INFORMATION:
APPLICANT: Griffais, R.
TITLE OF INVENTION: Chlamydia pneumoniae genomic sequence and polypeptides, fragments
TITLE OF INVENTION: thereof and uses thereof, in particular for the diagnosis, prevention
TITLE OF INVENTION: and treatment of infection
FILE REFERENCE: 9710-003-999
CURRENT APPLICATION NUMBER: US/09/198,452A
CURRENT FILING DATE: 1998-11-24
NUMBER OF SEQ ID NOS: 6849
SEQ ID NO 921
LENGTH: 391
TYPE: PRT
ORGANISM: Chlamydia pneumoniae
US-09-198-452A-921
Query Match 100.0%; Score 1939; DB 2; Length 391;
Best Local Similarity 100.0%; Pred. No. 9.3e-180;
Matches 389; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy    1 MHPKIEKRNSLPLTAVAPVFEESYHPSVATTVDYVDATTLSRHLTVLKDVIKEARNLDLG 60
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db    3 MHPKIEKRNSLPLTAVAPVFEESYHPSVATTVDYVDATTLSRHLTVLKDVIKEARNLDLG 62

Qy   61 KAFLTSMKQGFINTGTELAIIQASLADQSSRESRKKEEKIFHQHLGKAAPQAATATSGVQ 120
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db   63 KAFLTSMKQGFINTGTELAIIQASLADQSSRESRKKEEKIFHQHLGKAAPQAATATSGVQ 122

Qy  121 PTADPVADKMPLQSAFAYVLLDKYIPAQEEALYALGRELNLSGYAQNLFSPLLDMIKSFN 180
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  123 PTADPVADKMPLQSAFAYVLLDKYIPAQEEALYALGRELNLSGYAQNLFSPLLDMIKSFN 182

Qy  181 SAPINYNLGSYISQTSGTANFAYGYEMILSRYNNEVSQCRLDIASTVKAKAALANMSASV 240
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  183 SAPINYNLGSYISQTSGTANFAYGYEMILSRYNNEVSQCRLDIASTVKAKAALANMSASV 242

Qy  241 KANVSLTDAQKKQIEDIIASYTKSLDVIHTQLTDVMTNLASITFVPGLNKYDPSYRIVGG 300
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Db  243 KANVSLTDAQKKQIEDIIASYTKSLDVIHTQLTDVMTNLASITFVPGLNKYDPSYRIVGG 302

Qy  301 DLSIIALQNDEKVLVDGKVDITTAVNEGGLLNFFTTVLTDVQNYGDLAQTQQLMLDLELK 360
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  303 DLSIIALQNDEKVLVDGKVDITTAVNEGGLLNFFTTVLTDVQNYGDLAQTQQLMLDLELK 362

Qy  361 AMQQQWSLVSASLKLLNGMYTTVISGFKN 389
          ||||||||||||||||||||||||||||||
Db  363 AMQQQWSLVSASLKLLNGMYTTVISGFKN 391
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Sequence 855, Application US/09438185A
Patent No. 6822071
GENERAL INFORMATION:
APPLICANT: Stephens, Richard
APPLICANT: Mitchell, Wayne
APPLICANT: Kalman, Sue

APPLICANT: Davis, Ronald
APPLICANT: The Regents of the University of California
TITLE OF INVENTION: Chlamydia Pneumoniae Genome Sequence
FILE REFERENCE: 018941-000411US
CURRENT APPLICATION NUMBER: US/09/438,185A
CURRENT FILING DATE: 2002-03-13
PRIOR APPLICATION NUMBER: US 60/108,279
PRIOR FILING DATE: 1998-11-12
PRIOR APPLICATION NUMBER: US 60/128,606
PRIOR FILING DATE: 1999-04-08
NUMBER OF SEQ ID NOS: 1074
SOFTWARE: FastSEQ for Windows Version 3.0
SEQ ID NO 855
LENGTH: 391
TYPE: PRT
ORGANISM: Chlamydia pneumoniae
FEATURE:
OTHER INFORMATION: CPn0853
US-09-438-185A-855
Query Match 100.0%; Score 1939; DB 2; Length 391;
Best Local Similarity 100.0%; Pred. No. 9.3e-180;
Matches 389; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy       1 MHPKIEKRNSLPLTAVAPVFEESYHPSVATTVDYVDATTLSRHLTVLKDVIKEARNLDLG 60
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       3 MHPKIEKRNSLPLTAVAPVFEESYHPSVATTVDYVDATTLSRHLTVLKDVIKEARNLDLG 62

Qy      61 KAFLTSMKQGFINTGTELAIIQASLADQSSRESRKKEEKIFHQHLGKAAPQAATATSGVQ 120
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      63 KAFLTSMKQGFINTGTELAIIQASLADQSSRESRKKEEKIFHQHLGKAAPQAATATSGVQ 122

Qy     121 PTADPVADKMPLQSAFAYVLLDKYIPAQEEALYALGRELNLSGYAQNLFSPLLDMIKSFN 180
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     123 PTADPVADKMPLQSAFAYVLLDKYIPAQEEALYALGRELNLSGYAQNLFSPLLDMIKSFN 182

Qy     181 SAPINYNLGSYISQTSGTANFAYGYEMILSRYNNEVSQCRLDIASTVKAKAALANMSASV 240
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     183 SAPINYNLGSYISQTSGTANFAYGYEMILSRYNNEVSQCRLDIASTVKAKAALANMSASV 242

Qy     241 KANVSLTDAQKKQIEDIIASYTKSLDVIHTQLTDVMTNLASITFVPGLNKYDPSYRIVGG 300
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     243 KANVSLTDAQKKQIEDIIASYTKSLDVIHTQLTDVMTNLASITFVPGLNKYDPSYRIVGG 302

Qy     301 DLSIIALQNDEKVLVDGKVDITTAVNEGGLLNFFTTVLTDVQNYGDLAQTQQLMLDLELK 360
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     303 DLSIIALQNDEKVLVDGKVDITTAVNEGGLLNFFTTVLTDVQNYGDLAQTQQLMLDLELK 362

Qy     361 AMQQQWSLVSASLKLLNGMYTTVISGFKN 389
           |||||||||||||||||||||||||||||
Db     363 AMQQQWSLVSASLKLLNGMYTTVISGFKN 391
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12. No claims are allowed.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Primary Examiner
Art Unit 1645

NMM

April 12, 2007